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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,347	02/23/2004	Lawrence Restaino	536-3A	5893

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EXAMINER	
KOSSON, ROSANNE	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/784,347	RESTAINO, LAWRENCE	
	Examiner	Art Unit	
	Rosanne Kosson	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *10 and 11* is/are allowed.

6)☒ Claim(s) *1-9, 12-15* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.G.O.

DETAILED ACTION

Priority

This application repeats a substantial portion of prior Application No. 09/885,204, filed on August 20, 2001, and adds and claims additional disclosure not presented in the prior application (see p. 4 and the pending claims). Therefore, it is a continuation-in-part of the prior application. The first paragraph of the specification, however, states that the instant application is a continuation of the prior application. Appropriate correction is requested.

Allowable Subject Matter

Claims 10 and 11 are allowed.

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claims 1 and 12 recite, respectively, a plating medium for identifying any target bacteria and a method for detecting the presence of any target bacteria. The specification discloses a medium for detecting the presence of only one target bacterium, Salmonella, and method of using this medium to determine the presence of Salmonella in a sample.

Claims 1 and 12 also recite any enzyme that is produced by the reaction of the other bacteria (i.e., any non-target bacteria) with any first substrate and any second substrate, the first substrate reacting significantly more quickly with the enzyme than the second substrate. The specification discloses only one enzyme, β-galactosidase, and only group of its substrates in which one member of the group reacts significantly faster with the enzyme than another member of the group (see claims 3, 10, 14 and 16). Apart from the X-Gal/Y-Gal pair of β-galactosidase substrates in which one substrate, X-Gal, is disclosed as reacting significantly faster that the other substrate, Y-Gal (see p. 4 of the specification), pairs from this group with one fast reacting and one slowly reacting member are not indicated. Nevertheless, the relative reaction rates of these nine substrates could be determined by one of ordinary skill in the art.

Thus, there is no evidence that other representative species of such large and varied genera- target bacteria, enzymes, pairs of first and second substrates- were in the possession of the inventors at the time of filing. To satisfy the written description aspect of 35 U.S.C. 112, first paragraph, for a claimed genus of molecules, it must be

clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. Because only one target bacterium, one enzyme and one group of substrates are disclosed, claims 1-9 and 12-16 fail to satisfy the written description requirement.

Claims 1-9 and 12-15 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a plating medium that identifies the target bacterium Salmonella, and a method of detecting the presence of the target bacterium Salmonella, does not reasonably provide enablement for a plating medium that identifies any target bacteria or a method of detecting the presence of any target bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. As discussed above, because only one enzyme and one group of substrates that may be used in the plating medium are disclosed, the plating medium is able to identify the presence of Salmonella only.

As a result, the scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to determine that

other bacteria may be detected or identified by the claiming plating medium and method of its use. Undue experimentation would also be required to determine which other enzymes and pairs of substrates would work in the claimed plating medium and method.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary (immense, because Applicants assert that any target bacteria may be identified and that any substrate pair may be used in the claimed medium, as long as one member of the pair reacts more quickly with an enzyme than the other member, without naming the target bacteria, the enzymes or the substrates beyond one example of each), (2) the amount of direction or guidance presented (guidance is presented for only one target bacterium, one enzyme and one pair of substrates), (3) the presence or absence of working examples (one plating medium is

described on p. 7), (4) the nature of the invention (a plating medium that can identify or detect the presence of any target bacterium based on the activity of any enzyme in any non-target bacterium for which a fast reacting substrate and a slowly reacting substrate are present in the medium), (5) the state of the prior art (a plating medium that can identify or detect the presence of the target bacterium Salmonella based on the activity of β-galactosidase with two of its substrates, one of which produces a colored product and one of which does not, as well as a plating medium that can identify or detect the presence of various enteric bacteria based on the activity of i) β-galactosidase with a substrate that produces a colored product and ii) β-glucuronidase with a substrate that produces a colored product, preferably of a different color), (6) the relative skill of those in the art (very high, that of highly trained research scientist), (7) the predictability or unpredictability of the art (see below), and (8) the breadth of the claims (broad, as discussed above).

With respect to the quantity of experimentation necessary, to demonstrate that a plating medium can identify or detect the presence of any target bacterium based on the activity of any enzyme in any non-target bacterium for which a fast reacting substrate and a slowly reacting substrate are present in the medium, many experiments would have to be conducted under a wide range of conditions. In these experiments, many different agar media would have to be prepared, each of which contains at least one pair of substrates, the pair being a fast reacting and a slowly reacting substrate for the same enzyme. This enzyme would have to be present in at least one bacterium in the sample that is plated on the medium. Thus, there is the complication in each case that

one would have to expect the enzyme-containing bacterium to be present in the sample. The results of the experiments would have to show that a number of different target bacteria can be identified by a number of such differential plating media, each medium containing a different pair of substrates.

Such experimentation is necessary because the specification describes only one differential plating medium, and it is designed to identify Salmonella in a mixed culture of enteric bacteria. One set of carbon sources that Salmonella can metabolize is disclosed, one enzyme that is not present in Salmonella but is present in most of the other bacteria is disclosed, and one set of substrates for the enzyme is disclosed. There is a large gap between Applicants' disclosure and the amount of information needed to formulate other differential plating media to identify other target organisms in mixed culture based on other carbon sources and other pairs of substrates, with fast and slowly reacting members. One of skill in the art would have to experiment unduly to fill in this gap.

To be commensurate in scope with a broad claim for a plating medium able to identify any target bacterium based on the activity of any enzyme with any pair of substrates yielding a colored product and having substantially different reaction rates, a great deal of guidance must be present in the specification to enable one of skill in the art to prepare a number of these substrates. As noted above, only one plating medium is disclosed. Nevertheless, if additional data obtained from experiments using additional plating media are available, Applicants are invited to submit these data for consideration.

Regarding predictability, each microorganism behaves differently, each requiring its own conditions and growth medium. Each enzyme behaves differently and reacts with a different substrate or set of substrates. Therefore, one of skill in the art could not predict, given the plating medium described in the specification, that a plating medium containing a different carbon source and two substrates (or two different substrates) that produce a colored product upon reaction with a different enzyme, one substrate reacting faster than the other, would be able to identify the presence of a particular organism in a mixed culture. Although claim 8 is limited to the identification of Salmonella and substrates of β-galactosidase, the claim recites that any substrates of β-galactosidase may be used. It cannot be predicted that all substrates of β-galactosidase will yield products of the second color or that when any two substrates are incorporated into the medium, one will react significantly faster than the other.

Accordingly, claims 1-9 and 12-15 fail to satisfy the enablement requirement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 1 recites a first substrate that "injects color into the medium of a second color responsive to the presence of an enzyme produced by a reaction between other bacteria and said first substrate," and a second substrate that "injects color into the medium of substantially the same color as

the second color responsive to the presence of an enzyme produced by a reaction between other bacteria and said second substrate." This claim language is confusing and difficult to read.

To make the claim comprehensible, Applicant may wish to amend claim 1, parts (3) and (4) as follows: a first substrate that does not react with the target bacteria and that generates a second color in the medium where it is acted upon by an enzyme produced by other bacteria, the second color contrasting with the first color and the color of the medium, (4) a second substrate that does not react with the target bacteria and that generates substantially the second color in the medium where it is acted upon by the enzyme produced by other bacteria, the first substrate reacting with the enzyme in a significantly shorter time than the second substrate.

If the medium were the second color before the second color was injected (blue), then the medium would not work as a differential test medium for identifying a target bacterium because the original medium color (colorless or yellow) and the first color (red) would not be visible. Also, the medium cannot be both the second color and a color substantially the same as the second color. But, if the second color appears in the medium in colonies of bacteria that contain β-galactosidase, or in the vicinity of these colonies, in accordance with the suggested claim language, the original color and the first color would be visible. Described in this way, the claimed medium would function for its intended purpose.

Claims 8 and 12 in parts (3) and (4) are similar to claim 1 and contain the same confusing and tortuous claim language. Applicant may wish to amend these claims as

follows: 8. (3) a first chromogenic substrate that does not react with Salmonella and that generates a second color in the medium where it is acted upon by β-galactosidase, the second color contrasting with the first color and the color of the medium, (4) a second chromogenic substrate that does not react with Salmonella and that generates substantially the second color in the medium where it is acted upon by the enzyme produced by other bacteria, the first substrate reacting with the enzyme in a significantly shorter time than the second substrate. Claim 8 also contains a typographical error, as it recites components 1-4 and 6, rather than components 1-5. Applicant may wish to correct this error as well.

Claim 12 may be amended to read as follows: 12. (3) a first substrate that does not react with the target bacteria and that generates a second color in the medium where it is acted upon by an enzyme produced by other bacteria, the second color contrasting with the first color and the color of the medium, (4) a second substrate that does not react with the target bacteria and that generates substantially the second color in the medium where it is acted upon by the enzyme produced by other bacteria, the first substrate reacting with the enzyme in a significantly shorter time than the second substrate.

The following references are cited to show further the state of the art: Monget et al. (US 5,434,056), which discloses a differential plating medium for identifying Salmonella, and Roth et al. (US 5,726,031), which discloses a differential plating medium for the identification of various types of gram negative bacteria, including

Salmonella. The agar medium of Monget et al. comprises a carbohydrate source (a sugar mixture such as yeast extract), a pH indicator (neutral red), an inhibitor of gram-positive bacteria (bile salts) and first and second substrates for β-galactosidase (X-gal and IPTG). The first substrate reacts significantly more quickly with the enzyme than the second substrate, which is a poorer substrate (see col. 4, line 22, to col. 6, line 8). The difference between the claimed medium and that of Monget et al. is that the second substrate in Monget et al. does not produce a colored product. The agar medium of Roth et al. comprises a carbohydrate source (a sugar mixture such as yeast extract and sorbitol), a pH indicator (phenol red), an inhibitor of gram-positive bacteria (bile salts) and first and second chromogenic substrates that generate colored products. The colors produced may the same or different. To identify as many bacteria as possible, it is preferred that the colors be different. The first substrate may be X-gal (see col. 4, lines 27-37, col. 9, line 34, to col. 12, line 39, and col. 14, lines 30-61). The difference between the claimed medium and that of Roth et al. is that the two substrates are substrates for different enzymes. The first substrate is hydrolyzed by a β-galactosidase, and the second substrate is hydrolyzed by a β-glucuronidase.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-

2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

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2005-06-01

ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653